

PYXIS REGULATORY CONSULTING, INC.

4110 136th St. NW
Gig Harbor, WA 98332

☒ Inprocessed
☒ BACKED
☒ WAIVER
Phone: 253-853-7369
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www.PyxisRC.com

February 15, 2011

WAIVERS Beane!
D387942
3/24/11

COURIER DELIVERY

Russell Wasem, Chemical Review Manager
Document Processing Desk (DCI/PRD)
Office of Pesticide Programs (7508P)
One Potomac Yard (South Building)
2777 South Crystal Drive
Arlington, VA 22202

RE: Imidacloprid (Chemical No. 129099, Case No. 7605)
Submission of 90-Day Response for Ensystex III, Inc. (EPA Company No. 82957) (ID No. RR-129099-30160)

Dear Mr. Wasem,

On behalf of Ensystex III, Inc. (EPA Company Number 129099), please find Ensystex's 90-Day response to the Imidacloprid Registration Review Generic Data Call-In for Imidathor and ENS-010A (EPA Reg. Nos. 82957-1 and 82957-4, respectively).

In support of this submission, we enclose the following:

1. Completed Data Call-In Response Form
2. Completed Requirements Status and Registrant's Response Form
3. Certification of Attempt to Enter into an Agreement with Registrants for Development of Data
4. Waiver request for certain data requirements
5. Letter of authorization

Please contact me by telephone (253-853-7369) or by e-mail (Janelle@PyxisRC.com) if you have any questions or need any additional information.

Sincerely,



Janelle Kay

Enclosures

United States Environmental Protection
Agency Washington, D.C. 20460

OMB Approval 2070-0174

OMB Approval 2070-0107
OMB Approval 2070-0057

DATA CALL-IN RESPONSE

INSTRUCTIONS: Please type or print in ink. Please read carefully the attached instructions and supply the information requested on this form.
Use additional sheet(s) if necessary.

1. Company Name and Address ENSYSTEX III, INC. 4110 136TH ST., NW GIG HARBOR, WA 98332		2. Case # and Name Chemical # and Name 129099 Imidacloprid		3. Date and Type of DCI and Number 10-Nov-2010 GENERIC ID # RR-129099-30160	
4. EPA Product Registration	5. I wish to cancel this product regis- tration volun- tarily	6. Generic Data		7. Product Specific Data	
		6a. I am claiming a Generic Data Exemption because I obtain the active ingredient from the source EPA regis- tration number listed below.	6b. I agree to satisfy Generic Data requirements as indicated on the attached form entitled "Requirements Status and Registrant's Response."	7a. My product is an MUP and I agree to satisfy the MUP requirements on the attached form entitled "Requirements Status and Registrant's Response."	7b. My product is an EUP and I agree to satisfy the EUP requirements on the attached form entitled "Requirements Status and Registrant's Response."
82957-1 82957-4			yes yes	N.A. N.A.	N.A. N.A.
8. Certification I certify that the statements made on this form and all attachments are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine, imprisonment or both under applicable law.				9. Date	
Signature and Title of Company's Authorized Representative <u>my Agent</u>				2/15/11	
10. Name of Company <u>Ensyntex III Inc</u>				11. Phone Number <u>253-853-7309</u>	

United States Environmental Protection
Agency Washington, D.C. 20460

OMB Approval 2070-0174

OMB Approval 2070-0107
OMB Approval 2070-0057

REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE

INSTRUCTIONS: Please type or print in ink. Please read carefully the attached instructions and supply the information requested on this form.
Use additional sheet(s) if necessary.

1. Company Name and Address ENSYSTEX III, INC. 4110 136TH ST., NW GIG HARBOR, WA 98332		2. Case # and Name Chemical # and Name 129099 Imidacloprid		3. Date and Type of DCI and Number 10-Nov-2010 GENERIC ID # RR-129099-30160					
4. Guideline Requirement Number	5. Study Title	P R O T O C O L	Progress Reports			6. Use Pattern	7. Test Substance	8. Time Frame (Months)	9. Registrant Response
			1	2	3				
835.4300	<u>Environmental Fate Data Requirements (Conventional Chemical)</u> Aerobic aquatic metabolism					H, R, U, BB, I, K, II, Q, A, B, C, J, T, S	TGAI or PAIRA	24	3
	<u>Nontarget Plant Protection Data Requirements (Conventional Chemical)</u>								
850.4100	Terrestrial plant toxicity, Tier 1 (seeding emergence) (5, 10)					H, R, U, BB, I, K, II, Q, A, B, C, J, T, S	TEP	12	3
850.4150	Terrestrial plant toxicity, Tier 1 (vegetative vigor) (3, 11, 12)					H, R, U, BB, I, K, II, Q, A, B, C, J, T, S	TEP	12	3
850.4400	Aquatic plant toxicity test using Lemna spp. Tiers I and II (4)					H, R, U, BB, I, K, II, Q, A, B, C, J, T, S	TEP or TGAI	12	3
875.2300	<u>Post-Application Exposure Data Requirements (Conventional Chemical)</u> Indoor surface residue dissipation (1, 13, 14)					H, R, U, BB, I, K, II, Q, A, B, C, J, T, S	TEP	12	3
	<u>Terrestrial and Aquatic Nontarget Organisms Data Requirements (Conventional Chemical)</u>								
850.3040	Field testing for pollinators (2, 15)					H, R, U, BB, I, K, II, Q, A, B, C, J, T, S	TEP	24	9
870.7800	<u>Toxicology Data Requirements (Conventional Chemical)</u>								
	Immunotoxicity					H, R, U, BB, I, K, II, Q, A, B, C, J, T, S	TGAI	12	3
10. Certification I certify that the statements made on this form and all attachments are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine, imprisonment or both under applicable law Signature and Title of Company's Authorized Representative <i>Danely Agent</i>							11. Date 2/15/11		
12. Name of Company <i>Enysstex III, Inc</i>							13. Phone Number <i>253-853-7369</i>		

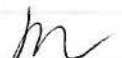
United States Environmental Protection
Agency Washington, D.C. 20460

OMB Approval 2070-0174

OMB Approval 2070-0107
OMB Approval 2070-0057

REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE

INSTRUCTIONS: Please type or print in ink. Please read carefully the attached instructions and supply the information requested on this form.
Use additional sheet(s) if necessary.

1. Company Name and Address ENSYSTEX III, INC. 4110 136TH ST., NW GIG HARBOR, WA 98332		2. Case # and Name Chemical # and Name 129099 Imidacloprid		3. Date and Type of DCI and Number 10-Nov-2010 GENERIC ID # RR-129099-30160					
4. Guideline Requirement Number	5. Study Title	P R O T O C O L	Progress Reports			6. Use Pattern	7. Test Substance	8. Time Frame (Months)	9. Registrant Response
			1	2	3				
Special Study	Residue Analysis of Nectar and Pollen in Flowering Crops (7,8,9,17)					H, R, U, BB, I, K, II, Q, A, B, C, J, T, S	TEP	48	9
Special Study	Seed Leaching Study Using TEP (6,16)					H, R, U, BB, I, K, II, Q, A, B, C, J, T, S	TEP	12	9
Initial to indicate certification as to information on this page (full text of certification is on page one).							Date 2/15/11		

**Waiver Requests for Submission of Generic Data for Ensystex III, Inc.
Imidacloprid (Case Number 0176, Chemical Code 078003)**

Guideline Number	Guideline Title	Waiver Request Justification
850.3040	Field Testing for Pollinators	<p>The Ecological Effects Data Justifications for Imidacloprid in the Problem Formulation stated that "Due to the potential for toxic exposure of pollinators from imidacloprid translocated in treated crops..." Ensystex III, Inc's (Ensystex) registrations are specifically limited to <i>non-crop uses only</i>, including ornamentals, turf, indoor uses, and terrestrial outdoor areas such as playgrounds, parks, structures and buildings.</p> <p>The potential for exposure of Ensystex's imidacloprid to pollinators is very limited as it is not used on flowering agricultural crops such as blueberries, citrus and stone fruits. Because the justification specifically referenced "crops" (believed to be agricultural crops) and because of the limited label registered by Ensystex, these data are not applicable to Ensystex. Therefore, Ensystex respectfully requests a waiver from the submission of these data.</p>
Special Study	Residue Analysis of Nectar and Pollen Flowering Crops	<p>In the amended Final Work Plan and the Data Call-In for Imidacloprid, EPA requires field residue studies to determine the residues in leaves, nectar and/or pollen in citrus, blueberries, stone fruits (apples or cherries), cotton and corn. As mentioned above, Ensystex's label is limited to non-crop uses only, including ornamentals, turf, indoor uses, and terrestrial outdoor areas such as playgrounds, parks, structures and buildings.</p> <p>The crops required in the Data Call-In are not on Ensystex's label and therefore, any exposure or residue to pollinators from the use of imidacloprid on these crops is not related to Ensystex. Ensystex believes that these data are not applicable and respectfully requests a waiver from the submission of these data.</p>
Special Study	Seed Leaching Study Using TEP	<p>Ensystex's products are not labeled for use as a seed treatment (the labels are specifically limited to non-food uses only as explained above). That is, no seeds are treated with Ensystex's products. Therefore, these data are not applicable to Ensystex's registered use patterns and it respectfully requests a waiver from the submission of these data.</p>



United States Environmental Protection Agency
Washington, D.C. 20460
CERTIFICATION OF ATTEMPT TO ENTER INTO AN
AGREEMENT WITH REGISTRANTS FOR
DEVELOPMENT OF DATA

Form Approved.

OMB Nos. 2070-0057;
2070-0107; 2070-0122;
2070-0164

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 15 minutes per response including time for reading the instructions, searching existing data sources, gathering and maintaining the data needed and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, Collection Strategies Division (2822T), U.S. Environmental Protection Agency, 1200 Pennsylvania Avenue, N.W., Washington, DC 20460. Do not send the form to this address.

Please fill in blanks below

Company Name

Ensystex III, Inc.

Company Number

82957

Chemical Name

Imidacloprid

EPA Chemical Number

129099

I Certify that:

My company is willing to develop and submit the data required by EPA under the authority of the Federal Insecticide, Rodenticide and Fungicide Act (FIFRA), if necessary. However, my company would prefer to enter into an agreement with one or more registrants to develop jointly or share in the cost of developing data.

My firm has offered in writing to enter into such an agreement. That offer was irrevocable and included an offer to be bound by arbitration under section 3(c)(2)(B)(iii) of FIFRA if final agreement on all terms could not be reached otherwise. This offer was made to the following firm(s) on the following date(s):

Name of Firm(s)

Bayer Environmental Science; Lanxess Corporation; Celsius Property B.V. Amsterdam (NL); United Phosphorus, Inc.; Nufarm, Inc.; Nufarm Americas, Inc.; Bayer Cropscience LP; Hebei Veyong Bio-Chemical Co., Ltd.; Advan LLC; Amtide, LLC; Albaugh Inc.; Control Solutions, Inc.; Rotam Limited; Source Dynamics, LLC; Sharda Worldwide Exports Pvt. Ltd.

Date of Offer

Feb. 14, 2011

Certification:

I certify that I am duly authorized to represent the company name above, and that the statements that I have made on this form and all attachments therein are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

Signature of Company's Authorized Representative

Date

2/15/11

Name and Title (Please Print or Type)

Janelle Kay, Agent

ENSYSTEX III, Inc.

2709 Breezewood Ave., P. O. Box 2587, Fayetteville, NC 28302-2587 USA
Telephone - 1-910-484-6163 x 203 Fax - 1-910-484-3378 Email david@ensystex.com

November 2, 2005

To Whom It May Concern:

Re: Letter of Authorization

Dear Sir or Madam:

Please let this letter serve to confirm that Pyxis Regulatory Consulting, Inc. is authorized to act as agent for Ensytex III, Inc. (EPA Company Number pending), before the U.S. Environmental Protection Agency and state governmental agencies in all matters regarding our pesticide registrations pursuant to the Federal Insecticide, Fungicide and Rodenticide Act ("FIFRA"), 7 U.S.C. § 136 et seq. and state law.

If you have any questions, please do not hesitate to contact me.

Sincerely,



David Nimocks
Chairman

cc: Pyxis Regulatory Consulting, Inc.

Notary



Norman A. Stackley, Notary Public
My commission expires 4-21-06